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White Paper on Health 4.0 Interoperability Perspectives

Background

The White Paper "Service-oriented Device Point-of-Care Interoperability (SDPi)" was published 23rd of August, 2019.

This white paper "Health 4.0 Interoperability Perspectives" refers to the following action items which Uwe took during the SDC@IHE web conference on August 1, 2019:

1. Creating an additional architectural concept perspective that could be added to the SDPi-White Paper indicating connection to personalized digital health, including FHIR and exploration of the integration with cloud-based "web apps".
2. Creating a concept perspective for the relationship between SDC@IHE and the U.S. ONC published "TEFCA" trusted exchange framework guide that may be valuable for recognizing how SDPi could fit in the broader digital health infrastructure space.

The broader perspective: Health 4.0

The fourth industrial revolution, termed 4.0, will have a major impact, on how health is delivered to health citizens in the not so far future. Health 4.0 stands for personalized digital assisted health services, systems, automized healthcare processes and people, which are connected in networks. Health 4.0 applications will provide added value to all stakeholders which participate in the care process. The future for app-driven and cloud-based economies are considered bright, which also holds for the health domain. App architectures are already driving digital platforms and infrastructures for healthcare, including telemedicine.

A common understanding on following topics will contribute to build a safe, secure and effective healthcare ecosystem and infrastructure:

1) underlying medical and web-standards-based reference architecture models and associated cloud federation models,
2) a concept of a "Health and IoT Service Applications Platform 4.0 (HISAP4)" including health standards-based APIs,
3) design considerations regarding the placement of cyber-secured health services within health networks security zones,
4) an implementation approach of smart medical device systems and services based on the FHIR resources model and IHE integration profiles,
5) the role of artificial intelligence/algorithm-supported smart healthcare processes including regulatory challenges,

6) FHIR/IHE-based microservices architecture concepts which support collaborative business models,
7) demonstrators of smart sensors and services for personalized recording of vital signs including a telemonitoring application,
8) a vison of a virtual marketplace which trades quality-assured health services of cyber-physical medical systems in regulated health networks.

Application programming interfaces (APIs) are major drivers transforming the app-driven economy in healthcare. APIs bring a new level of connectivity and data sharing to multiple applications, regardless of their platforms, data structures, and underlying technologies.

SDPi and IHE service profiles and IHE service operations

Figure 1a illustrates in most simple terms an SDPi service exchanged between a device observation service provider (DOSP, actor 1) and a device service consumer (DOSC, actor 2). Figure 1b includes an SDPi service API, which exchanges service data between application 1 (DOSPA, actor 1) and application 2 (DOSCA, actor 2).

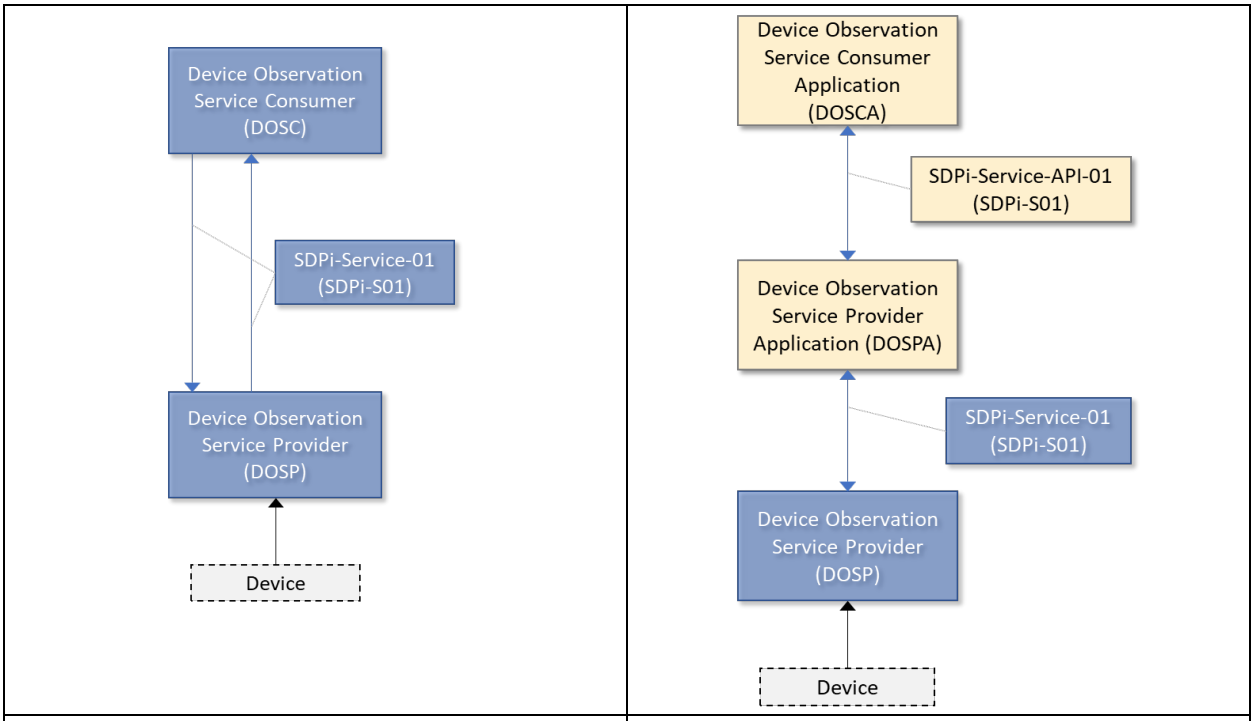
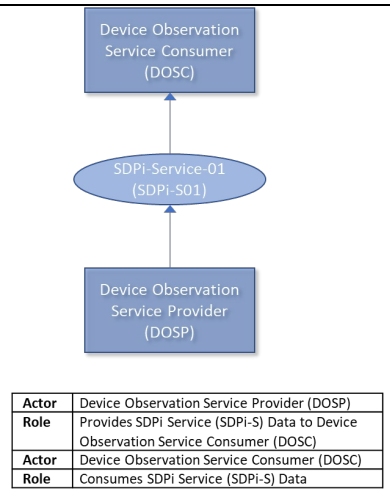


Fig 1a: SDPi integration profile 01 with service actors (DOSP and DOSC) and a SDPi service (SDPi-S01)

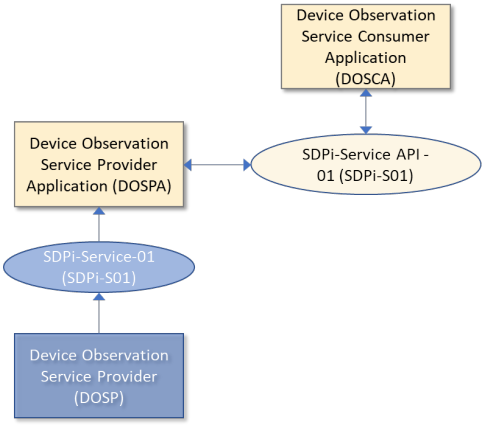
Fig. 1b: SDPi application integration profile 01 with service application actors (DOSPA and DOSCA) and a SDPi service API

Figure 2a illustrates a SDPi service/use case 01 with service actors (DOSP and DOSC) and a SDPi set of service operations between a device observation service provider (DOSP, actor 1) and a device service consumer (DOSC, actor 2). Figure 2b includes a SDPi service/use case API 01 with service application actors (DOSPA and DOSCA) and a SDPi service API.



Actor	Device Observation Service Provider (DOSP)
Role	Provides SDPi Service (SDPi-S) Data to Device Observation Service Consumer (DOSC)
Actor	Device Observation Service Consumer (DOSC)
Role	Consumes SDPi Service (SDPi-S) Data

Fig 2a: SDPi service/use case 01 with service actors (DOSP and DOSC) and a SDPi set of service operations



Actor	Device Observation Service Provider Application(DOSPA)
Role	Provides SDPi Service API (SDPi-API) to Device Observation Service Consumer Application (DOSCA)
Actor	Device Observation Service Consumer Application (DOSCA)
Role	Consumes SDPi Service (SDPi-S) Data

Fig. 2b: SDPi service/use case API 01 with service application actors (DOSPA and DOSCA) and a SDPi service API

SDPi-API specifications and other service API interoperability testing

These considerations will pose a challenge on interoperability specifications of future "Connectathons". Future interoperability specifications of connected systems in distributed networks will require API-specifications, which are drawn from medical device systems standards, health IT standards, and web standards, including definition of profiles and transactions, on how data are exchanged between applications and services. Participating vendors in future Connectathons will be challenged to prove standards-based API interoperability by successfully binding data and data structure of their vendor-API to a specified, standardized-based profile-API, utilizing a standardized health domain information model, e.g. the ISO/IEEE 11073-10201 (DIM) for health/medical devices. The hierarchy of the 11073-DIM could be also represented and specified with bundled HL7 FHIR resources.

Future Connectathon interoperability testing (here termed "Connectathons 4.0") will include testing of API-specifications of connected cyber-physical medical systems in disparate networks. The figure below illustrates an IoT scenario of connected devices, systems, services and applications which communicate through web service APIs. Standardized API gateways will facilitate web service communication between connected systems in distinct networks. Disparate networks of connected systems and applications may reside on premises at the point of care (PoC), in the cloud (private, hybrid, public) and in remote locations. Connectathon 4.0 operators are challenged to provide smart API test generators which automate smart API testing of connected sensors, devices, systems, and applications including APIs for user interfaces.

The figure below depicts a generic API-connected scenario of coupled multi-vendor devices, systems, clients and applications (including user interfaces). This kind of an API-connected systems scenario may serve as a generic Connectathon "system of systems" setup for interoperability testing of defined API-profile specifications in the future.

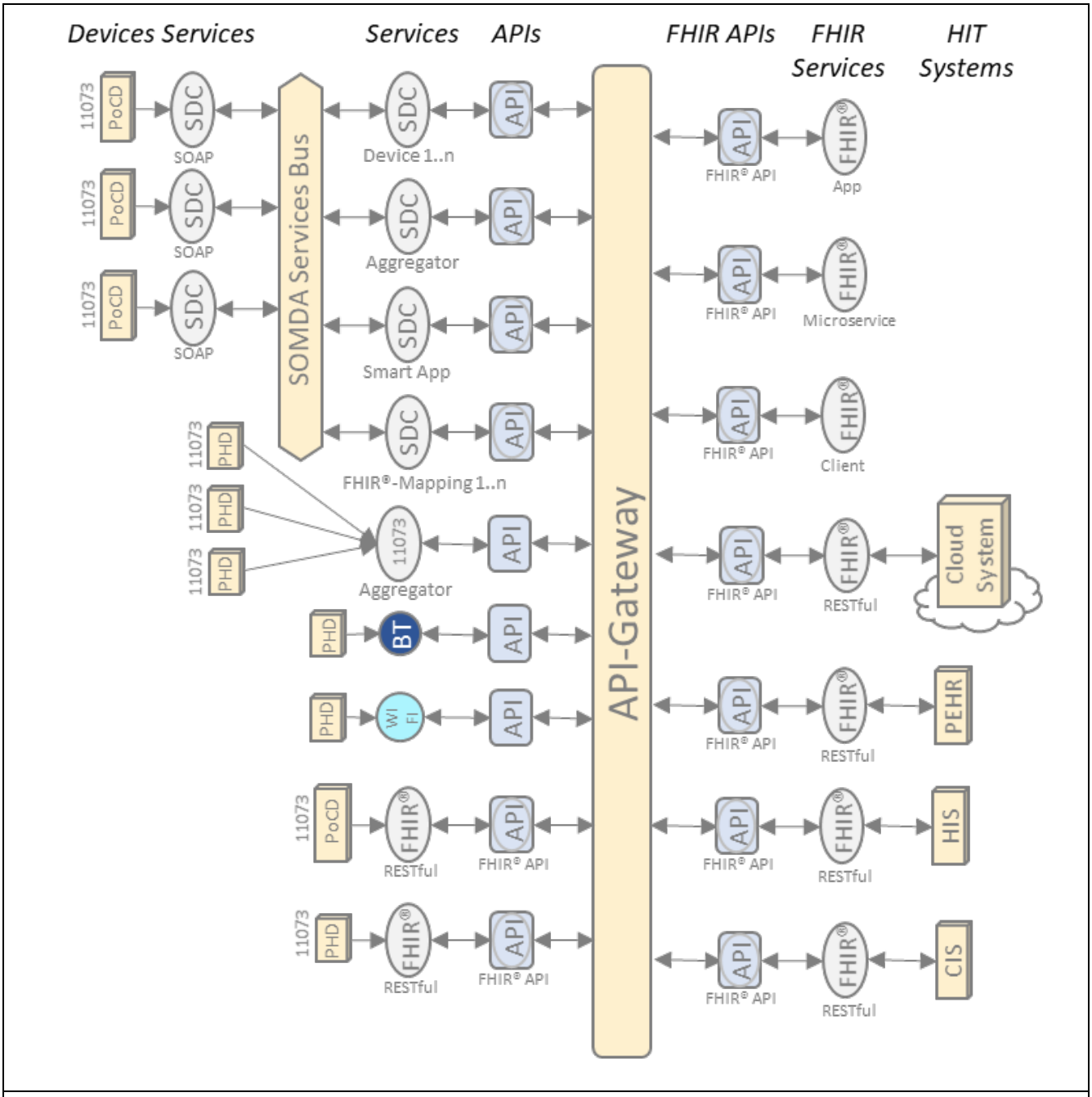


Fig. 3: Concept of a generic "system of systems" setup for "Connectathon 4.0" interoperability testing of standards-based service API specifications

Trusted Exchange Framework and Common Agreement (TEFCA)

"*Draft 2 of the Trusted Exchange Framework and Common Agreement (TEFCA), released on April 19, 2019, outlines a common set of principles, terms, and conditions to support the development of a Common Agreement that would help enable nationwide exchange of electronic health information (EHI) across disparate health information networks (HINs). The TEFCA is designed to scale EHI exchange nationwide and help ensure that HINs, health care providers, health plans, individuals, and*

many more stakeholders have secure access to their electronic health information when and where it is needed"[1].

The TEFCA common principles are designed to facilitate trust among Health Information Networks (HINs). The principles are:[2]

> **Principle 1 – Standardization:**
> Adhere to industry and federally recognized standards, policies, best practices, and procedures.
>
> **Principle 2 – Transparency:**
> Conduct all exchange and operations openly and transparently.
>
> **Principle 3 – Cooperation and Non-Discrimination:**
> Collaborate with stakeholders across the continuum of care to exchange EHI, even when a stakeholder may be a business competitor.
>
> **Principle 4 – Privacy, Security, and Safety:**
> Exchange EHI securely and in a manner that promotes patient safety, ensures data integrity, and adheres to privacy policies.
>
> **Principle 5 – Access:**
> Ensure that individuals and their authorized caregivers have easy access to their EHI.
>
> **Principle 6 – Population-Level Data:**
> Exchange multiple records for a cohort of individuals at one time in accordance with applicable law to enable identification and trending of data to lower the cost of care and improve the health of the population.

Future Interoperability Connecthatons 4.0 (e.g. @HIMSS) may consider methodologies and testing procedures for a system of connected HINs, which demonstrate compliance with the principles listed above. Guidelines for the integration of HL7 FHIR®-standards in IHE-profiles will lead to standardized Health 4.0 APIs, which can be tested in setups of API-connected HIN, as outlined in Fig. 3.

[1] https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement
[2] Slide 7 https://www.healthit.gov/sites/default/files/page/2019-04/TEFCADraft2UsersGuide.pdf